

REMARKS

I. Summary of Office Action

Claims 1-27 are pending in this case. The Examiner withdraws claims 2-11 and 15-17 pursuant to 37 C.F.R. § 1.142(b) as being drawn to a non-elected species. The Examiner objects to the specification as failing to provide proper antecedent basis for the claimed terms. The Examiner rejects claims 12, 13, and 18-27 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not adequately described in the specification. Claims 12, 13, and 18-27 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite in scope. The Examiner rejects claims 1, 12, 13, and 18-27 under 35 U.S.C. § 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Taylor U.S. patent 3,952,742 (hereinafter "Taylor"). Claim 14 is rejected under 35 U.S.C. § 103(a) as obvious over Taylor.

II. Summary of Applicants' Reply

Applicants have amended the specification to further clarify terms used in the claims. Applicants have canceled claim 12 without prejudice. Applicants have amended claims 18, 21, and 24. Applicants respectfully traverse the Examiner's withdrawal of claims 15-17 as being drawn to a non-elected species. The Examiner's objections

and rejections are respectfully traversed.

III. Applicants' Remarks on the Examiner's Withdrawal of Claims 15-17

The Examiner contends that, contrary to remarks in applicants' August 13, 2003 Reply to Office Action, claims 15-17 do not read on the elected species of FIGS. 5 and 7a-8a. Applicants respectfully traverse.

The Examiner asserts that claim 15 does not read on the elected species because "the distal portion of longitudinal structure (e.g., 210) is not resiliently biased to deflect laterally" (page 2, ¶ 1 of Office action). Contrary to the Examiner's assertion, applicants submit that the feature "longitudinal structure" in claim 15 refers to the entirety of the apparatus disposed coaxially within tube 210 in FIG. 7a (i.e., components 220, 230, 240, and 250). Accordingly, applicants further submit that tube 210 of FIG. 7a corresponds to the feature "elongated guide structure" in claim 15.

As set forth in applicants' independent claim 1, the longitudinal structure is substantially aligned with and guided by the elongated guide structure. A distal portion of the longitudinal structure is adapted to penetrate the side wall of the patient's tubular body organ by distal motion of the longitudinal structure relative to the guide structure. Accordingly, applicants submit that

distal portion 252 of component 250 constitutes a distal portion of the longitudinal structure and is shown to be resiliently biased to deflect laterally (see FIGS. 7a and 7b, and page 18, lines 18-23 of specification).

The Examiner similarly asserts that claim 16 does not read on the elected species because "it is the elongated guide structure 250 rather than any portion of the longitudinal structure that makes an initial penetration of the side wall" (page 2, ¶ 1 of Office action). Applicants again submit that the term "longitudinal structure" in both claims 15 and 16 refer to the entirety of the apparatus disposed coaxially within tube 210 in FIG. 7a. Therefore, for example, distal end 252 of member 250 may be used to make an initial penetration of the side wall of the patient's tubular organ structure (see page 19, lines 3-16 of specification).

Furthermore, applicants respectfully submit that claim 17 also reads on the elected species of FIGS. 5 and 7a-8a because FIGS. 7b-7g show that any of members 250, 240, 230, or 220 may be threaded at a distal end (also see page 18, lines 24-28 of specification).

Accordingly, applicants respectfully submit that claims 15-17 read upon the elected species of FIGS. 5 and 7a-8a and request that these claims be rejoined in the prosecution of the present application.

IV. Applicants' Reply to the Examiner's  
Objection to the Specification

The Examiner objects to the specification as failing to provide proper antecedent basis for the claimed terms "elongated guide structure" and "longitudinal structure" and requested that these terms be defined in the specification. Applicants have amended the specification to obviate the Examiner's objection. Therefore, applicants respectfully request that this objection be withdrawn.

V. Applicants' Reply to the Examiner's Rejection  
Based on 35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 12, 13, and 18-27 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have canceled claim 12 without prejudice and amended claims 18, 21, and 24. The Examiner's rejection is respectfully traversed.

The Examiner contends that there is no basis in the original disclosure of parent application No. 08/745,618 for certain features of claims 13 and 18-27. In particular, the Examiner pointed to the feature of claim 13 that requires the distal portion of the longitudinal structure to be sharpened to facilitate

penetration of the side wall (page 3, ¶ 1 of Office action). The Examiner also pointed to claims 18, 21, and 24 for language that defines the "distal portion of the longitudinal structure" as a tubular member (page 3, ¶ 1 of Office action).

Applicants note that claims 13 and 18-27 were originally filed in parent application No. 08/745,618 as claims 98 and 103-112. Therefore, these claims form a part of the original disclosure of parent application No. 08/745,618. Moreover, applicants have amended claims 18, 21, and 24 to further define the "guide structure" rather than the "distal portion of the longitudinal structure."

Therefore, applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 112, first paragraph has been obviated and should be withdrawn.

VI. Applicants' Reply to the Examiner's Rejection Based on 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 12, 13, and 18-27 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Examiner contends that the scope of these claims are unclear for the reasons set forth in the Examiner's above rejection under 35 U.S.C. § 112, first

paragraph. Further, the Examiner points out that there is no antecedent basis for the term "said apertures" in claim 24 (see page 3, ¶ 2 of Office action).

Applicants have canceled claim 12 without prejudice and have amended claims 18, 21, and 24 to further define the "guide structure" rather than the "distal portion of the longitudinal structure." Applicants have also amended claim 24 to provide proper antecedent basis for all claimed features.

Therefore, in view of the applicants' foregoing remarks regarding the Examiner's rejection under § 112, first paragraph, applicants submit that the Examiner's rejection under § 112, second paragraph has been obviated and should be withdrawn.

VII. Applicants' Reply to the Examiner's Prior Art Rejections Based on Taylor

The Examiner rejects claims 1, 12, 13, and 18-27 under 35 U.S.C. § 102(b) as anticipated by or, alternatively, under 35 U.S.C. § 103(a) as obvious over Taylor. Claim 14 is rejected under 35 U.S.C. § 103(a) as unpatentable over Taylor. Applicants have canceled claim 12 without prejudice and amended claims 18, 21, and 24. The Examiner's rejections are respectfully traversed.

Applicants' invention, as defined by independent claim 1, is directed toward an instrument for creating an aperture through a side wall of a patient's tubular body organ structure. The instrument includes an elongated guide structure that is longitudinally insertable into the patient's tubular body organ structure from an insertion location to the point at which the aperture is to be created. The instrument further includes a longitudinal structure that is substantially aligned with and guided by the guide structure. The longitudinal structure is movable relative to the elongated guide structure. A distal portion of the longitudinal structure is adapted to penetrate the side wall of the patient's tubular body organ structure when forced against the side wall by a sufficient amount of distal motion of the longitudinal structure relative to the guide structure.

Taylor is directed toward a cannula-type cardiac resuscitation instrument consisting of flexible tube 12 and rigid catheter-like needle 14. The needle acts as a rigid penetration and carrying device for carrying the flexible tube into a proper position in the patient's heart. Rigid needle 14 is inserted into a central axial passage of flexible tube 12, which is carried into position by the needle through the cardiac wall. After penetration of the cardiac tissue, the needle may be withdrawn to leave the

flexible tube in position for injecting medication directly into the heart.

The Examiner contends that rigid needle 14 of Taylor meets all the features of applicants' claimed "guide structure" (see page 4, ¶ 1 of Office action). The Examiner further contends that flexible tube 12 of Taylor meets all the features of applicants' claimed "longitudinal structure" and includes distal portion 12c adapted to penetrate tissue (see page 4, ¶ 1 of Office action).

Accepting, *arguendo*, the Examiner's contention that rigid needle 14 serves as the "guide structure," applicants maintain that Taylor still fails to show or suggest the feature of independent claim 1 that requires a longitudinal structure with a distal portion adapted to penetrate the side wall of the patient's tubular body organ structure by distal motion of the longitudinal structure relative to the guide structure.

Taylor shows that flexible tube 12 must be rigidified and carried by needle 14 during insertion into the patient and that needle tip 14a is intentionally exposed beyond flexible tube end 12c to provide means for puncturing a person's chest and heart walls (see col. 1, lines 39-45 of Taylor). Applicants submit that Taylor does not assign any tissue penetrating ability to flexible tube 12 and that, in essence, flexible tube 12 and tube

end 12c are merely configured to follow in the path created by rigid needle 14.

Applicants further submit that Taylor fails to show or suggest that flexible tube 12 is adapted to penetrate the side wall of a patient's tubular body organ structure by distal motion relative to the guide structure. In contrast, Taylor shows that needle 14 and tube 12 remain in the same relative position with respect to one another until the positioning of tube 12 in the patient is complete and needle 14 is withdrawn to derigidify tube 12 (see FIG. 1 and col. 3, lines 16-54 of Taylor). Therefore, applicants submit that Taylor fails to show or suggest all the features of applicants' independent claim 1.

With reference to the Examiner's § 103(a) rejection based on Taylor, applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. In particular, applicants submit that the Examiner has failed to provide any objective evidence of a suggestion or motivation, in Taylor or in the general knowledge of the art, to modify the flexible tube of Taylor to penetrate the side wall of a patient's tubular body organ structure by distal movement relative to the guide structure.

In fact, Taylor teaches away from applicants' novel and unobvious approach by a) providing a flexible tube that is incapable of tissue penetration by itself, b)

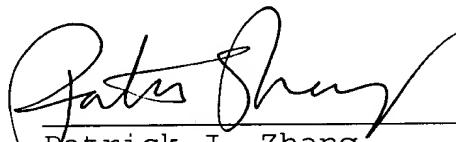
using a rigidifying needle to penetrate tissue and carry the flexible tube into position within the patient, and c) maintaining the flexible tube and the rigid needle in the same relative position with respect to one another during the tissue penetration. Therefore, applicants submit that one of ordinary skill in the art would not be motivated to make such a wayward modification. Applicants further submit that, even if it is possible, modifying Taylor to reconfigure its flexible tube for tissue penetration by distal movement relative to the rigid needle would alter the very principle of operation for the Taylor instrument.

Accordingly, for at least the foregoing reasons, applicants submit that independent claim 1 and dependent claims 13, 14 and 18-27 are both novel and unobvious over Taylor and respectfully request that the rejections based on Taylor be withdrawn.

VIII. Conclusion

In view of the foregoing, applicants submit that claims 1 and 13-27 are in condition for allowance. Reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,

  
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